UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,486	07/27/2001	Itzhak Ofek	2290.00123	1947

7590 11/03/2003

KOHN & ASSOCIATES
Suite 410
30500 Northwestern Highway
Farmington Hills, MI 48334

EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	7

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No.	Applicant(s)	
	09/916,486	OFEK ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 16-23* is/are pending in the application.

4a) Of the above claim(s) *2,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

Claims 1-2 and 16-23 are currently pending.

Claims 1 and 16-21 are currently under consideration.

Claims 2 and 22-23 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1 and 16-21) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the Group II (method of use of Group I composition) should be considered with the Group I invention to promote efficient prosecution. This argument was considered but not found persuasive for the reasons provided in the restiction including patentable distinctness and burdensome search e.g. the individual groups have acquired a separate status in the art due to their recognized divergent subject matter which necessitates different and separately burdensome manual/computer bibliographic searches. However, upon the allowance of Group I, the Examiner will consider an applicant request for rejoinder regarding the Group II invention. With respect to Group III invention it is noted that applicant has failed to provide arguments refuting the restriction of these claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2 and 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Priority

3. Applicant has not fully complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Although present the cross reference to 08/772,021 should be updated to reflect the patenting of this application.

It is also noted that the present application (09/159,626: filed 9/24/98) is a CIP application of 08/772,021 (12/19/96).

In this regard, claims 1, 16-21 contain NEW MATTER (e.g. anti-adhesion activity against H.Pylori) which was not present in the 09/159,626 application. Thus claims 1 and 17-21 are denied 35 USC 120 priority; and for purposes of prior art is afforded the filing date of the present application (e.g. 9/24/98). With regard to new claim 16 it is further pointed out that this claim lacks written description under 35 USC 112, first paragraph (see rejection below) and thus is denied 35 USC 121; and thus for purposes of prior art is afforded a filing date of 7/27/01 (or later).

Claim Objections

Claim 16 is objected to because of the following informalities: "A anti-microbial ... " should be --- An antimicrobial ... ---- . Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A In claims 1 and 19, the molecular weight (MW) limitation is indefinite regarding the units (e.g. daltons, kilodaltons etc.) And the means used to measure molecular weight (e.g. gel chromatograph? Or acidic or basic PAGE conditions?). The means and conditions of MW measurement are important since different weight amounts may result from different means of measurement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (LACK OF WRITTEN DESCRIPTION).

Claim 16 is directed to a pharmaceutical composition comprising pharmaceutical acceptable carriers/diluents and :

a. an isolated vaccinium juice fraction

b. having anti-adhesion activity against H. pylori.

Accordingly, the claimed composition is devoid of:

a. any composition structure whatsoever;

b. or any specific isolation protocol

but defines the composition as being "an isolated adhesion inhibitory fraction from vaccinium" which has "anti-adhesion activity against H. pylori. E.g. applicant's claimed isolated compostion is defined in a purely functional manner. In su

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

In the present instance, the claimed invention contains no identifying characteristics regarding chemical structure; and the small number of species PF-1, PF-2 and NDM defined by their method of isolation and/or a defined set of physicochemical properties (e.g. MW ; elemental analysis NMR, UV etc.) is not representative of the presently claimed composition.

In this regard, applicant is referred to *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) (and subsequent cases) and the

resulting "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001). It is additionally noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

With regard to the description requirement, Applicants' attention is further directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)]. In Eli Lilly, the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others. Id. At 1568, 43USPQ2d at 1405. Nor did the specification describe a sufficient number of species within the very broad genus to

indicate that the inventors had made a generic invention, i.e., that they had possession of the breadth of the genus, as opposed to merely one or two such species. E.g. See *Enzo Biochem. Inc.v. Gen-Probe Inc.*, Case No. 01-1230 (Fed. Cir. July 15, 2002) ("EnzoII").

Accordingly, the claimed pharmaceutical composition lacks written description.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ofek et al., "Anti-Escherichia Coli Adhesion Activity of Cranberry and Blueberry Juices", Toward Anti-Adhesion Therapy for Microbial Diseases, edited by Kahane and Ofek (Plenum Press, N.Y. 1996) pages 179-183 alone or if necessary further in view of the present specification (e.g. examples and figures) to provide evidence of inherency. See MPEP 2131.01(d).

Claim 16 is directed to a pharmaceutical composition comprising pharmaceutical acceptable carriers/diluents and :

a. an isolated vaccinium juice fraction

b. having anti-adhesion activity against H. pylori.

In claims 1 and 18, the isolated vaccinium juice fraction is further described as having:

MW >= 14,000; by possessing carbon (43-51%) and hydrogen (4-5%) with no nitrogen/sulfur/chlorine and NMR/UR spectra; coaggregation reversal/inhibition; adhesion inhibition against P fimbriated bacteria/oral bacteria and inhibitory fraction of between 1 microgram and 10 mg/ml. Claim 17 claims the fraction which includes PF-1, PF-2 and NDM.

The Ofek et al. reference discloses a water-eluted fraction (e.g. PF-1; 100 mg: see e.g. Table 1) isolated from cranberry/blueberry juices which appears to be identical to the composition presently claimed and which possesses pharmaceutical activity (e.g. anti-adhesion). Accordingly, the reference meets the critical pharmaceutical composition claim limitations; and other parameters not specifically recited by the reference (e..g NMR/UV: anti-H.pylori etc.) would be deemed to be inherently present in a composition which is identical to that presently claimed. Additionally, the specification examples/figures demonstrate that the PF-1 prior art fraction inherently possesses the same molecular weight; phyisicochemical parameters (e.g. NMR/IR etc.) and pharmaceutic inhibitory and (anti) aggregation activities as presently claimed. To the extent that the amounts of the active agent are not specifically taught (e.g. 1 microgram to 10 mg) it is noted that the making of pharmaceutical compositions and the determination of optimum dosages is well within the skill of the art and thus would be obvious to one of ordinary skill at the time of applicant's invention.

9. Claims 1 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofek et al., "Anti-Escherichia Coli Adhesion Activity of Cranberry and Blueberry Juices", Toward Anti-Adhesion Therapy for Microbial Diseases, edited by Kahane and Ofek (Plenum Press, N.Y. 1996) pages 179-183 alone or if necessary further in view of the present specification (e.g. examples and figures) to provide evidence of inherency. See MPEP 2131.01(d) and Walker et al. US Pat. No. 5,525,341 (6/96: filed 2/94 or earlier).

Claim 16 is directed to a pharmaceutical composition comprising pharmaceutical acceptable carriers/diluents and :

a. an isolated vaccinium juice fraction

b. having anti-adhesion activity against H. pylori.

In claims 1 and 18, the isolated vaccinium juice fraction is further described as having:

MW >= 14,000; by possessing carbon (43-51%) and hydrogen (4-5%) with no nitrogen/sulfur/chlorine and NMR/UR spectra; coaggregation reversal/inhibition; adhesion inhibition against P fimbriated bacteria/oral bacteria and inhibitory fraction of between 1 microgram and 10 mg/ml. Claim 17 claims the fraction which includes PF-1, PF-2 and NDM.

The Ofek et al. reference discloses a water-eluted fraction (e.g. PF-1; 100 mg: see e.g. Table 1) isolated from cranberry/blueberry juices which appears to be identical to the composition presently claimed and which possesses pharmaceutical activity (e.g. anti-adhesion). Accordingly, the reference meets the critical pharmaceutical composition claim limitations; and other parameters not specifically recited by the reference (e..g

NMR/UV: anti-H.pylori etc.) would be deemed to be inherently present in a composition which is identical to that presently claimed. Additionally, the specification examples/figures demonstrate that the PF-1 prior art fraction inherently possesses the same molecular weight; phyisicochemical parameters (e.g. NMR/IR etc.) and pharmaceutic inhibitory and (anti) aggregation activities as presently claimed. To the extent that the amounts of the active agent are not specifically taught (e.g. 1 microgram to 10 mg) it is noted that the making of pharmaceutical compositions and the determination of optimum dosages is well within the skill of the art and thus would be obvious to one of ordinary skill at the time of applicant's invention.

The Ofek et al. reference differs from the presently claimed invention (e.g. present claims 19-21 in failing to disclose the use of the reference composition as a "fortified food composition".

In this regard, it is noted that the Ofek composition is isolated from blueberry juices thus demonstrating its compatibility in a fruit food composition. Secondly, Ofek et al. specifically recognizes that "cranberry juices" (and their contained components) are recommended by physicians e.g. to prevent/treat urinary infections (e.g see Ofek at pages 179-180). Thirdly, the making of fortified food compositions is conventionally known in the art.

In this respect, the Walker et al. patent suggests the use as a "food supplement" (e.g. Walker et al at col. 2, lines 39-53) of Vaccinium plant (e.g. cranberry) extracts which possess anti-bacterial properties similar to that presently claimed; and thus would

motivate one of oridinary skill in the art to utilize the Ofek et al. composition as a fortified food composition.

Accordingly, it would obvious in view of the Walker et al. Patent reference to utilize the Ofek composition in a fortified food (e.g. juice) composition as presently claimed .

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,840,322 in view of '322 examples (e.g. to PF-1, PF-2 and NDM) and applicant's own specification (e.g. examples/figures) as evidence of inherency.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims disclose non-food oral hygiene compositions and methods directed to an agent thereof which possess anti-microbial adhesion activity (e.g. against oral bacteria; and against P fimbriated bacteria) including PF-1 ,

PF-2 and NDM which necessarily inherently possess the presently claimed MW , elemental analysis, NMR/IR and other inhibitory activities as presently claimed and as exemplified in applicant's own specification for PF-1; PF-2 and NDM; which would provide motivation to one of ordinary skill in the art to make anti-microbial adhesion pharmaceutical compositions within the scope of the presently claimed invention; thus rendering the present claims obvious.

12. Claims 1 and 16-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,840,322 in view of '322 examples (e.g. to PF-1, PF-2 and NDM) and applicant's own examples/figures as evidence of inherency taken alone or if necessary further in view of Walker et al. U.S. Pat. No. 5,525,341 (6/96: filed 2/94 or earlier).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims disclose non-food oral hygiene compositions and methods directed to an agent thereof which possess anti-microbial adhesion activity (e.g. against oral bacteria; and against P fimbriated bacteria) including PF-1 , PF-2 and NDM which necessarily inherently possess the presently claimed MW , elemental analysis, NMR/IR and other inhibitory activities as presently claimed and as exemplified in applicant's own specification for PF-1; PF-2 and NDM; which would provide motivation to one of ordinary skill in the art to make anti-microbial adhesion pharmaceutical compositions within the scope of the presently claimed invention; thus rendering the present claims obvious.

With respect to present claims 19-21 drawn to fortified food compositions (e.g. fruit juice such as cranberry as carrier) the '322 patent claims taken alone would provide motivation to one of ordinary skill in the art to formulate a fruit juice product (e.g. cranberry/blueberry) which is "fortified" or "enriched" with the patented composition in order to obtain the benefits therefrom (e.g anti-bacterial); and thus render obvious the presently claimed "fortified fruit juice food composition" as presently claimed.

Alternatively, the Walker et al. patent suggests the use as a "food supplement" (e.g. Walker et al at col. 2, lines 39-53) of Vaccinium plant (e.g. cranberry) extracts which possess anti-bacterial properties similar to that presently claimed.

Accordingly, it would obvious in view of the Walker et al. Patent reference to utilize the '322 composition in a fortified food (e.g. juice) composition as presently claimed.

Claims 1 and 16-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,303,125 (10/16/01) and its disclosure (e.g. examples) as evidence of inherency.

Although the conflicting claims are not identical, they are not patentably distinct from each other because patent claims 1-3 teach antimicrobial adhesion pharmaceutical compositions and fortified food composition comprised thereof in which the antimicrobial adhesion composition is within the scope of the presently claimed invention regarding

all of the presently claimed parameters (e.g. MW ; elemenal analysis; NMR/UR ; coaggregation; adhesion inhibition but differs in only two respects:

Fraction composition is between 1 microgram and 10 mg/ml and the fraction possesses anti-adhesion activity against H. pylori.

However, the '125 patent claims clearly encompass isolated fractions (e.g. PF-1; PF-2 and NDM) of between 1 microgram and 10 mg/ml and the fraction possesses anti-adhesion activity against H. pylori as demonstrated in the '125 disclosure examples/tables thus rendering obvious fractions which are clearly within the scope of the presently claimed invention (e.g. see present claim 17).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
October 31, 2003